

## **REMARKS**

### **Introduction**

Claims 7-8 are pending. Claims 7-8 have been amended. Support for the amendments can be found throughout the specification, for example, in the claims as filed, in Figure 4, and in paragraphs [0007], [0043], [0044], [0045], and [0046]. No new matter has been added.

Claims 1-6 and 9-19 have been cancelled without prejudice to the subject matter disclosed therein. Applicant expressly reserves the right to pursue the subject matter of the cancelled claims in this application or in another application.

### **Rejection under 35 U.S.C. §112**

#### *A. 112 second - indefiniteness*

The Examiner has rejected claims 7, 8, 17 and 18 under 35 U.S.C. §112 as allegedly being indefinite. Specifically, the Examiner has stated that the claim language "KCNE4" and the language covering derivatives thereof is allegedly indefinite. Applicants traverse.

To expedite prosecution, Applicant has amended the claims to remove the derivatives language and to specify that the protein KCNE4 referred to in the claims is shown in SEQ ID NO: 1 which appears, for example, in Figure 4 of the application. In view of the specification, one of skill in the art will be able to determine the metes and bounds of the amended claims so this rejection has been overcome. Applicant respectfully requests that this rejection be withdrawn.

#### *B. 112 first – utility/written description*

The Examiner has rejected claims 7, 8, 17 and 18 under 35 U.S.C. §112 as allegedly lacking a specific or substantial credible utility because of allegedly insufficient written description for the claimed genus. Applicants traverse.

To expedite prosecution, the claims have been amended to recite that KCNE4 has the specific structure of SEQ ID NO:1. The language directed to derivatives of this protein that appears to have triggered this genus/species rejection has been removed. In fact, Applicant has amended the claims in accord with the Examiner's suggestion that claims directed to isolated polypeptides comprising the amino acid sequence of SEQ ID NO:1 meet the written description requirement of 35 U.S.C. §112. *See* Office Action on pg. 10.

For at least these reasons, Applicant believes that this rejection is now moot in view of the amended claims. Withdrawal of this rejection is respectfully requested.

**Rejection under 35 U.S.C. §101**

The Examiner has rejected claims 7, 8, 17 and 18 under 35 U.S.C. §101 as allegedly lacking a specific and substantial credible asserted utility. Applicants traverse.

As amended, independent claim 7 is directed to methods of screening for a compound that decreases Alzheimer's disease, wherein the compound is a modulator of one or more substances selected from the group consisting of: (i) a gene coding for KCNE4 protein as shown in SEQ ID NO:1, (ii) a transcription product of the gene coding for KCNE4 protein as shown in SEQ ID NO:1, and (iii) a translation product of the gene coding for KCNE4 protein as shown in SEQ ID NO:1, said method comprising: (a) administering a test compound to a test animal which is predisposed to developing or has already developed symptoms of Alzheimer's disease; (b) measuring the activity and/or level of one or more substances recited in (i) to (iii); (c) measuring the activity and/or level of one or more substances recited in (i) or (iii) in a matched control animal which is predisposed to developing or has already developed symptoms of Alzheimer's disease and to which animal no such test compound has been administered; (d) comparing the activity and/or level of the substance in the animals of step (b) and (c), wherein an alteration in the activity and/or level of substances in the test animal indicates that the test compound is a modulator of Alzheimer's disease.

Applicant has provided the sequence for the KCNE4 protein and experimental data showing that patients diagnosed with Alzheimer's disease show a differential expression of the

KCNE4 protein in their brain tissue when compared to a healthy brain tissue control. *See, e.g.*, Figures 2, 3, 11 and 12 and paragraphs [0058]-[0069]. Moreover, Applicant has provided the working example found in Example 1 explaining the methods used to produce this data. Further description of the claimed screening methods as well as a definition of what constitutes a "modulator" are provided in paragraphs [0007], [0043], [0044], [0045], and [0046]. Taken together, one of skill in the art will appreciate that compounds found to be modulators of KCNE4 as shown in SEQ ID NO: 1 have a specific and credible utility for treating Alzheimer's patients in view of at least the evidence in the specification.

Accordingly, the rejection of the claims under 35 U.S.C. §101 as allegedly lacking utility is improper. Applicant respectfully requests that this rejection be withdrawn.

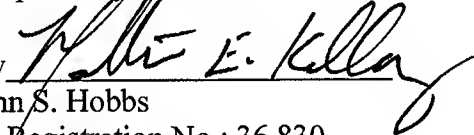
**CONCLUSION**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR § 1.17, including extension of time fees pursuant to 37 CFR § 1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Dated: *April 13, 2009*

Respectfully submitted,

By   
Ann S. Hobbs

Registration No.: 36,830

Matthew E. Kelley

Registration No.: 55,887

VENABLE LLP

P.O. Box 34385

Washington, DC 20043-9998

(202) 344-4000

(202) 344-8300 (Fax)

Attorney/Agent For Applicant